DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 11, 2015

Quality Medical Supply, Inc.
Julie Solomon
CEO
13174 W. Foxfire Drive, Suite B-132
Surprise, AZ 85378

Re: K150381
Trade/Device Name: Aqua Cleanse
Regulation Number: 21 CFR§ 876.5220
Regulation Name: Colonic irrigation system
Regulatory Class: II
Product Code: KPL
Dated: August 5, 2015
Received: August 7, 2015

Dear Julie Solomon,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150381

Device Name
AQUA CLEANSE

Indications for Use *(Describe)*
THIS DEVICE IS INTENDED FOR COLON CLEANSING WHEN MEDICALLY INDICATED, SUCH AS BEFORE RADIOLOGICAL OR ENDOSCOPIC EXAMINATION.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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SECTION 5 510(k) SUMMARY

DATE OF SUBMISSION:	JUNE 6, 2015
SUBMITTER NAME:	QUALITY MEDICAL SUPPLY
SUBMITTER ADDRESS:	13174 W. FOXFIRE DRIVE SUITE B-132 SURPRISE, AZ 85378
CONTACT:	JULIE SOLOMON
TELEPHONE:	(623) 640-4646
EMAIL:	JULIE@QMSAZ.COM
DEVICE TRADE NAME:	AQUA CLEANSE
COMMON NAME:	COLONIC IRRIGATION SYSTEM DISPOSABLE RECTAL SPECULUM KITS
CLASSIFICATION NAME:	COLONIC IRRIGATION SYSTEM (21 CFR 876.5220)
510(K) SUBMISSION NUMBER:	K150381
510(k) TYPE:	TRADITIONAL
PREDICATE DEVICE:	HC-1 CLASSIC (K131852) MANUFACTACTURER: TRANSCENDENCIAS COMERCIALES SL TRANSCOM

DEVICE DESCRIPTION:

The proposed device "Aqua Cleanse" is for colon cleansing when medically indicated such as before radiological or endoscopic examination. It introduces water at a comfortable temperature into the large intestine. It fills and empties water into and out of the colon thus cleansing it of its contents. The device is equipped with a pressure regulated safety system; a self-contained cleaning system, and flow regulator. It is used with the accessory, disposable rectal speculum kits.

The associated disposable kit is intended to introduce water into the colon through a speculum inserted into the rectum to assist with the evacuation of the contents of the lower colon. This is a single-use only kit.

NOTE: This is the first submission for the above mentioned device and disposable rectal speculum kits. There have been no prior submissions.

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SECTION 5 510(k) SUMMARY

SUMMARY OF COMPARISON WITH PREDICATE DEVICE:

In the establishment of substantial equivalence, the Aqua Cleanse as compared to the previously cleared HC-1 (K131852), manufactured by Transcendencias Comerciales SL Transcom, in Spain.

The following table summarizes the similarities of the principal technological characteristics and features of both predicate and new devices. From this table, it can be established that the Aqua Cleanse device and the predicate device are very similar.

COMPRISON TABLE

	Characteristic/Feature	PROPOSED DEVICE	PREDICATE DEVICE
		AQUA CLEANSE	HC-1 CLASSIC (K131852)
1	Cabinet Construction	Aluminum	Steel
2	Dimensions	21” X 17” X 4.5”	38” X 23” X 4.7”
3	Installation Type	Fixed	Fixed
4	Filters	3 Stage	2X 5pm Stage
5	U.V. light	NO	YES
6	Cleaning System	Automatic	Automatic
7	Timer	Yes	Yes
8	Flow Control	Yes	Yes
9	Pressure Gauge	Yes 0 – 2 PSI	Yes 0 – 250 MBAR
10	Temperature Gauge	Yes 99 – 100 Fahrenheit	Yes 22 40 Celsius
11	Lighting	Yes – Waterproof LED	Yes – Fluorescent Protected

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SECTION 5 510(k) SUMMARY

ACCESSORY, DISPOSABLE RECTAL SPECULUM KITS:
QMS kits are comprised of 1 rectal speculum, 1 inflow waterline, and 1 out-flow waste hose. They have the same technological characteristics as, and are substantially equivalent to, the predicate Hydro kits and use the same three component manufacturers as Specialty Health Products "Speculum Collection". Manufactured in the US by: Smooth-Bor Plastics, Icon Injection Molding, and Kelpac Medical.

Where applicable (with internal body contact) these materials have been tested for skin irritation and toxicity. Testing was conducted by Nelson Laboratories. Please note: the testing was completed at Nelson Laboratories where they are certified to ANSI/AAMI/ISO 10993-5. Quality Medical Supply does not carry these certifications nor does our application require us to do so.

INTENDED USE:
This device is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examination.

SUMMARY DISCUSSION OF NON-CLINICAL DATA:
The Aqua Cleanse device has been subjected to bench testing to determine conformance to performance specifications and requirements taking account of its intended use as a colon irrigation system.

Functional testing showed correct operation of the Aqua Cleanse as per its intended use, specifically including:

- Pressure Safety
- Temperature Safety
- Electrical Safety
- Leak Resistant
- Colon hydrotherapy treatment in accordance with device performance specifications

Note: No animal or clinical testing was performed on the proposed device.

CONCLUSIONS:
According to the bench test results and all of the above information we note a remarkable comparison between the Aqua Cleanse device and the predicate device HC-1 Classic (as well as the accessory, disposable speculum kits) Bench test results proved safety and effectiveness when testing for accurate pressure and temperature range. The two devices are essentially the same when comparing: intended use, indications for use, safety, functionality, and operation of the legally marketed device.